

### **Amendments to the Claims**

This listing of claims will replace all prior versions, and listings, of claims in the application:

#### **Listing of Claims**

1. (currently amended) A catheter assembly comprising:

a catheter, the catheter comprising a catheter shaft and a balloon positioned at a distal end portion of the catheter shaft, the balloon including a first portion having a first outer diameter and a second portion having a second outer diameter that is different than the first outer diameter;

a rotatable sheath, the rotatable sheath rotatably disposed about at least a portion of the balloon, the rotatable sheath including a first portion having a first portion inner diameter and a second portion having a second portion inner diameter that is different than the first portion inner diameter, the first portion of the rotatable sheath being arranged axially adjacent the second portion of the rotatable sheath, the first portion of the rotatable sheath arranged in radial alignment with the first portion of the balloon and the second portion of the rotatable sheath arranged in radial alignment with the second portion of the balloon such that the rotatable sheath is longitudinally secured relative to the balloon when the balloon is in both an expanded state and an unexpanded state; and

a guidewire housing, the guidewire housing defining a guidewire lumen for passage of a guidewire therethrough, at least a portion of the guidewire housing being engaged to an outer surface of the rotatable sheath.

2. (previously presented) The catheter assembly of claim 1 wherein at least a portion of the guidewire housing is engaged to at least a proximal portion of the outer surface of the rotatable sheath.

3. (previously presented) The catheter assembly of claim 1 further comprising a stent, the stent being disposed about at least a portion of the rotatable sheath.

4. (original) The catheter assembly of claim 3 wherein at least a portion of the stent is disposed about at least a portion of the guidewire housing.

5. (previously presented) The catheter assembly of claim 1 wherein the rotatable sheath further comprises a third portion, at least the second portion of the rotatable sheath being positioned between the first portion and the third portion of the rotatable sheath, the first portion inner diameter being less than the second portion inner diameter.

6. (original) The catheter assembly of claim 5 wherein the rotatable sheath comprises a length, the second portion inner diameter being substantially constant along the length of the second portion.

7. (previously presented) The catheter assembly of claim 6 wherein the first portion inner diameter is tapered along the length of the first portion.

8. (original) The catheter assembly of claim 6 wherein the third portion defines a third portion inner diameter, the third portion inner diameter being less than the second portion inner diameter.

9. (original) The catheter assembly of claim 8 wherein the third portion inner diameter is tapered along the length of the third portion.

10-14. (canceled)

15. (original) The catheter assembly of claim 1 further comprising a stent, the stent being disposed about at least a portion of the rotatable sheath, the stent comprising a plurality of interconnected stent members wherein adjacent members define cell openings

16-20. (canceled)

21. (original) The catheter assembly of claim 15 wherein the rotatable sheath comprises a first end portion, a second end portion and an intermediate portion therebetween, the stent being disposed about the intermediate portion of the rotatable sheath, the first end portion having a first end portion outer diameter, the second end portion having a second end portion outer diameter, the intermediate portion having an intermediate portion outer diameter, the stent having a stent outer diameter, at least one of the first end portion outer diameter and the second end portion outer diameter being at least as great as the stent outer diameter.

22. (original) The catheter assembly of claim 21 wherein the first end portion outer diameter and the second end portion outer diameter are substantially equal to the stent outer diameter.

23. (canceled)

24. (original) The catheter assembly of claim 15 wherein at least a portion of the stent is coated with at least one therapeutic agent.

25. (previously presented) The catheter assembly of claim 24 wherein the at least one therapeutic agent is at least one non-genetic therapeutic agent selected from at least one member of the group consisting of: anti-thrombogenic agents; anti-proliferative agents; anti-inflammatory agents; antineoplastic/antiproliferative/anti-miotoxic agents; anesthetic agents; anti-coagulants; vascular cell growth promoters; vascular cell growth inhibitors; bifunctional molecules consisting of a growth factor and a cytotoxin; bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vasoactive mechanisms, and any combinations thereof.

26. (previously presented) The catheter assembly of claim 24 wherein the at least one therapeutic agent is at least one genetic therapeutic agent selected from at least one member of the group consisting of: anti-sense DNA and RNA; DNA coding for anti-sense RNA, tRNA or rRNA to replace defective or deficient endogenous molecules; angiogenic factors including

growth factors; cell cycle inhibitors including CD inhibitors, thymidine kinase ("TK") and other agents useful for interfering with cell proliferation; at least one of the family of bone morphogenic proteins ("BMP's"); dimeric proteins; molecules capable of inducing an upstream or downstream effect of a BMP, or the DNA's encoding them and any combinations thereof.

27. (original) The catheter assembly of claim 24 wherein the at least one therapeutic agent is at least one type of cellular material selected from at least one member of the group consisting of: cells of human origin (autologous or allogeneic); cells of non-human origin (xenogeneic) and any combination thereof.

28. (original) The catheter assembly of claim 27 wherein the cellular material is selected from at least one member of the group consisting of: side population cells; lineage negative cells; lineage negative CD34<sup>-</sup> cells; lineage negative CD34<sup>+</sup> cells; lineage negative cKit<sup>+</sup> cells; mesenchymal stem cells; cord blood cells; cardiac or other tissue derived stem cells; whole bone marrow; bone marrow mononuclear cells; endothelial progenitor cells; satellite cells; muscle derived cells; go cells; endothelial cells; adult cardiomyocytes; fibroblasts; smooth muscle cells; cultures of mesenchymal stem cells with 5-aza forces differentiation into cardiomyocytes; adult cardiac fibroblasts+5-aza; genetically modified cells; tissue engineered grafts; MyoD scar fibroblasts; Pacing cells; embryonic stem cell clones; embryonic stem cells; fetal or neonatal cells; immunologically masked cells; tissue engineered grafts; genetically modified cells; teratoma derived cells and any combinations thereof.

29. (previously presented) The catheter assembly of claim 24 wherein the at least one therapeutic agent comprises at least one polymer coating, the at least one coating selected from at least one member of the group consisting of: polycarboxylic acids; cellulosic polymers, including cellulose acetate and cellulose nitrate; gelatin; polyvinylpyrrolidone; cross-linked polyvinylpyrrolidone; polyanhydrides including maleic anhydride polymers; polyamides; polyvinyl alcohols; copolymers of vinyl monomers; polyvinyl ethers; polyvinyl aromatics; polyethylene oxides; glycosaminoglycans; polysaccharides; polyesters including polyethylene terephthalate; polyacrylamides; polyethers; polyether sulfone; polycarbonate; polyalkylenes

including polypropylene, polyethylene and high molecular weight polyethylene; halogenated polyalkylenes including polytetrafluoroethylene; polyurethanes; polyorthoesters; proteins; polypeptides; silicones; siloxane polymers; polylactic acid; polyglycolic acid; polycaprolactone; polyhydroxybutyrate valerate and blends and copolymers thereof; coatings from polymer dispersions; polysaccharides; hyaluronic acid; squalene emulsions; polyacrylic acid, a copolymer of polylactic acid and polycaprolactone; medical-grade biodegradable materials; polycaprolactone co butyl acrylate and other co polymers; Poly-L-lactic acid blends with DL-Lactic Acid; Poly(lactic acid-co-glycolic acid); polycaprolactone co PLA; polycaprolactone co butyl acrylate and other copolymers; Tyrosine-Derived Polycarbonates and arylate; poly amino acid; polyphosphazenes; polyiminocarbonates; polydimethyltrimethylcarbonates; biodegradable CA/PO<sup>4</sup>s; cyanoacrylate; 50/50 DLPLG; polydioxanone; polypropylene fumarate; polydepsipeptides; chitosan and Hydroxylpropylmethylcellulose; surface erodible material; maleic anhydride copolymers; zinc-calcium phosphate; amorphous polyanhydrides; sugar; carbohydrate; gelatin; biodegradable polymers; and polymers dissolvable in bodily fluids; A block copolymers; B block copolymers and any combinations thereof.

30. (original) The catheter assembly of claim 1 further comprising a lubricious coating, the lubricious coating positioned between at least a portion of the rotatable sheath and the catheter shaft.

31. (original) The catheter assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a hydrophilic polymer material.

32. (original) The catheter assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a tecophilic material.

33. (original) The catheter assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a first material and a second material.

34. (original) The catheter assembly of claim 33 wherein the rotatable sheath is at

least partially constructed from at least one material of the group consisting of hydrophilic polyurethanes, aromatic polyurethanes, polycarbonate base aliphatic polyurethanes, engineering polyurethane, elastomeric polyamides, block polyamide/ethers, polyether block amide, silicones, polyether-ester, polyester, polyester elastomer, polyethylene, polyamide, high-density polyethylene, polyetheretherketone, polyimide, polyetherimide, liquid crystal polymers, acetal, and any combination thereof.

35. (original) The catheter assembly of claim 33 wherein the first material is a polymer matrix and the second material is at least one distinct member of reinforcing material at least partially supported within the polymer matrix.

36. (original) The catheter assembly of claim 35 wherein polymer matrix is selected from at least one material from the group consisting of: hydrophilic polyurethanes, aromatic polyurethanes, polycarbonate base aliphatic polyurethanes, engineering polyurethane, elastomeric polyamides, block polyamide/ethers, polyether block amide, silicones, polyether-ester, polyester, polyester elastomer, polyethylene and any combination thereof.

37. (original) The catheter assembly of claim 35 wherein the reinforcing material is selected from at least one material of the group consisting of polyamide, polyethylene, high-density polyethylene, polyetheretherketone, polyimide, polyetherimide, liquid crystal polymers, acetal, and any combination thereof.

38. (previously presented) The catheter assembly of claim 1 wherein the rotatable sheath has a length substantially less than a length of the catheter.

39-50. (canceled)

51. (previously presented) The catheter assembly of claim 25 wherein the at least one therapeutic agent comprises at least one anti-thrombogenic agent selected from at least one member of the group consisting of: heparin, heparin derivatives, urokinase, and PPACK

(dextrophenylalanine praline arginine chloromethylketone).

52. (previously presented) The catheter assembly of claim 25 wherein the at least one therapeutic agent comprises at least one anti-proliferative agent selected from at least one member of the group consisting of: enoxaprin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid.

53. (previously presented) The catheter assembly of claim 25 wherein the at least one therapeutic agent comprises at least one anti-inflammatory agent selected from at least one member of the group consisting of: dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine.

54. (previously presented) The catheter assembly of claim 25 wherein the at least one therapeutic agent comprises at least one anesthetic agent selected from at least one member of the group consisting of: lidocaine, bupivacaine and ropivacaine.

55. (previously presented) The catheter assembly of claim 25 wherein the at least one therapeutic agent comprises at least one anti-coagulant selected from at least one member of the group consisting of: D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet peptides.

56. (previously presented) The catheter assembly of claim 25 wherein the at least one therapeutic agent comprises at least one vascular cell growth promoters selected from at least one member of the group consisting of: growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters.

57. (previously presented) The catheter assembly of claim 25 wherein the at least one therapeutic agent comprises at least one vascular cell growth inhibitor selected from at least

one member of the group consisting of: growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin.

58. (previously presented) The catheter assembly of claim 25 wherein the at least one therapeutic agent comprises at least one antineoplastic/antiproliferative/anti-miotic agent selected from at least one member of the group consisting of: paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors.

59. (previously presented) The catheter assembly of claim 26 wherein the at least one therapeutic agent comprises at least one growth factor selected from at least one member of the group consisting of: acidic and basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor  $\alpha$  and  $\beta$ , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor  $\alpha$ , hepatocyte growth factor and insulin like growth factor.

60. (previously presented) The catheter assembly of claim 26 wherein the at least one therapeutic agent comprises at least one of the family of bone morphogenic proteins ("BMP's") selected from at least one member of the group consisting of: BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16.

61. (previously presented) The catheter assembly of claim 26 wherein the at least one therapeutic agent comprises at least one dimeric proteins selected from at least one member of the group consisting of: homodimers, heterodimers, or combinations thereof.

62. (currently amended) A catheter assembly comprising:  
a catheter shaft;  
a balloon, the balloon arranged on the catheter shaft and having at least a first tapered end



and a second tapered end; and

a rotatable sheath, the rotatable sheath rotatably disposed about at least a portion of the balloon, the rotatable sheath including a first radially tapered end that is arranged in radial alignment with the first tapered end of the balloon and a second tapered end that is arranged in radial alignment with the second tapered end of the balloon, the first radially tapered end of the rotatable sheath being configured to complement the first tapered end of the balloon, the second tapered end of the rotatable sheath being configured to complement the second tapered end of the balloon, wherein the first and second tapered ends being configured to complement the first and second tapered ends of the balloon and longitudinally secure the rotatable sheath relative to the balloon when the balloon is in an expanded state and an unexpanded state.

63-64. (canceled)

65. (previously presented) The catheter assembly of claim 62, further comprising a stent, the stent being disposed about at least a portion of the rotatable sheath.

66. (previously presented) The catheter assembly of claim 62 further comprising a guidewire housing, the guidewire housing defining a guidewire lumen for passage of a guidewire therethrough, at least a portion of the guidewire housing being engaged to a portion of an outer surface of the rotatable sheath.

67. (previously presented) The catheter assembly of claim 62 wherein the first and second radially tapered ends of the rotatable sheath include a material having a higher hardness value than a portion of the rotatable sheath between the first and second radially tapered ends.